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10/779,569

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Alan G. Maloney

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EXAMINER

NEGIN, RUSSELL SCOTT

ART UNIT

PAPER NUMBER

1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/779,569 | Applicant(s) MALONEY ET AL. | |
| | Examiner RUSSELL S. NEGIN | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128-145 is/are pending in the application.
- 4a) Of the above claim(s) 134-136 and 143-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128-133 and 137-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Comments

Applicants' amendments and request for reconsideration in the communication filed on 31 March 2008 are acknowledged and the amendments are entered.

Claims 134-136 and 143-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 September 2006.

Claims 128-145 are pending, and claims 128-133 and 137-142 are examined in the instant Office action.

Information disclosure statement

The information disclosure statement filed on 31 March 2008 has been considered.

Withdrawn Objections/Rejections

The objections to the drawings are withdrawn in view of the amended set of drawings filed on 31 March 2008.

The objections to the specification are withdrawn in view of amendments filed to the specification and abstract.

The objections to claims 53-60 are withdrawn in view of amendments to the instant set of claims filed on 31 March 2008.

The rejections of claims 52-60, 64, 72-74, 77, 81-100, and 103 are withdrawn in view of amendments to the instant set of claims filed on 31 March 2008.

The rejections of claims 52-60, 64, 72-75, 77, 81-100, and 103 as failing to comply with the enablement requirement are withdrawn in view of applicant's arguments on pages 7-8 of the Remarks of 31 March 2008.

The rejections of claims 52-60, 64, 72-75, 77, 81-100, and 103 as being directed to non-statutory subject matter are withdrawn in view of amendments filed to the instant set of claims on 31 March 2008.

The rejections of claims 52-60, 64, 72-75, 77, 81-100, and 103 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of amendments filed to the instant set of claims on 31 March 2008.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following rejection is necessitated by applicant's amendments:

Claims 137-142 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 137-142 are drawn to computer readable media wherein page 6 of the specification (line 1-3) specifically states that the computer readable media encompasses carrier waves (i.e. signals), which, per se, are not statutory. See MPEP 2106. As the claims encompass embodiments which are nonstatutory subject matter, claims 137-142 are not statutory.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following rejection is necessitated by applicant's amendment:

Claims 131 and 140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Since step b of instant claim 128 involves "translating the genetic profile into one or more identifiers of a medical literature classification system for a medical literature database," and dependent claim 131 is further limiting where the medical literature classification system includes MeSH, instant claim 131 lacks written description because MeSH is continuously being updated and applicant does not have possession of MeSH in its current, or any future (updated) form. In other words, the translating step

involves searching databases in the form of MeSH present at the time of filing; applicant (at the time of filing) did not have possession of MeSH in any updated form.

The same type of analysis applies to claim 140.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following rejection is reiterated from the previous Office action:

Claims 128-129, 132-133, 137-138, and 141-142 are rejected under 35 U.S.C. 102(b) as being anticipated by Rappaport (US PG PUB 2002/0007285 A1; published 17 January 2003; filed 3 January 2001).

Independent claims 128 and 137 are drawn to a method and computer readable media of identifying medical literature (i.e. using computer code) comprising:

- a) receiving a genetic profile of a patient;
- b) translating the genetic profile into one or more identifiers of a medical classification system for a medical literature database;
- c) searching the medical literature database for medical literature articles relating to the one or more identifiers using an evidence based medicine filter; and
- d) identifying the articles on a user interface.

Rappaport discloses a method for use on a computer (paragraph 63, line 7-10) on computer readable medium (paragraph 21, lines 1-3) for receiving laboratory test results from a patient (for example, paragraph 5, figure 11) wherein the laboratory results may include genetic profile data (paragraph 32, lines 6-9). These results are associated with a code (paragraph 6, line 4) wherein the results in combination with the code are translated in concepts and contexts (for example, paragraph 79) that are used for identifying associated information that may include medical literature articles (for example, paragraph 105). Since the database of information being searched is a database of evidence based on medicine resources (for example, module 1017, figure 10; paragraph 21, lines 19-21) the retrieved articles are filtered based on relevance to evidenced-based medicine. Rappaport illustrates a user interface in Figure 1.

With respect to claims 129 and 138, Rappaport discloses obtaining genetic and genomic data as part of laboratory tests (paragraph 32, lines 6-9).

With respect to claims 132 and 141, Rappaport discloses that the documents present in the evidence based medicine database include clinical information in the form of related information on diagnoses and procedures (paragraph 196).

With respect to claims 133 and 142, Rappaport discloses that the information provided from the database can include results of randomized trials (a treatment has been validated) as well as suggestions as to whether or not a procedure or test should be performed (see paragraph 21).

Response to Arguments:

Applicant's arguments filed 31 March 2008 have been fully considered but they are not persuasive.

Applicant argues on pages 10-11 of the Remarks that ""Rappaport did not show searching the medical literature database for medical literature articles using an evidence based medicine filter." In support of this argument, applicant states the following:

However, the Evidence Database is not a medical literature database, such as MEDLINE or PubMed. Rather it is a database constructed for the purpose of serving Labstory.

This argument is not persuasive, because, absent a definition of "medical literature database" in the specification, the term is interpreted broadly and reasonably to be any database comprising medical information. Paragraph [0021] of Rappaport states with regards to "evidence based databases" that in each of the embodiments of the invention, this evidence based database may include medical information. Consequently, the evidence based database of Rappaport [i.e. lines 23-27 of paragraph 0021] is interpreted as a **medical literature database** that is searched for assisting the Labstory process as illustrated in Figure 10 of Rappaport. Applicant even states in the sentence bridging pages 10-11 of the Remarks:

When information about a lab test on a patient is received, e.g., into a Labstory document, the code associated with that test is used to query a database referred to as an "Evidence Database" to retrieve information from the Evidence Database for incorporation into the Labstory document. (see paragraph 0021 of Rappaport).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is reiterated:

35 U.S.C. 103 Rejection #1:

Claims 130 and 139 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rappaport as applied to claims 128-129, 132-133, 137-138, and 141-142 above, in further view of Davies et al. (US PGPUB 2003/0046114 filed 23 October 2001).

Claims 130 and 139 are further limiting wherein SNPs are analyzed.

Rappaport discloses a method for identifying medical literature as described above.

However, Rappaport does not detail SNPs.

Davies et al. disclose patient profiles including SNP information (for example, paragraph 19, paragraph 68).

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the medical literature searching of Rappaport by use of the SNP information of Davies wherein the motivation would have been that Davies et al. furthers the searching strategies of Rappaport by analyzing SNPs in order to improve patient care (for example, paragraph 26, lines 9-13).

Response to Arguments:

Applicant's arguments filed 31 March 2008 have been fully considered but they are not persuasive. Applicant argues that the reference of Davies et al. does not overcome the alleged deficiencies of Rappaport. As discussed above, the reference of Rappaport is not deficient; therefore the rejection is maintained.

The following rejection is NEWLY Applied based on evidence provided in the IDS of 31 March 2008:

35 U.S.C. 103 Rejection #2:

Claims 131 and 140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rappaport as applied to claims 128-129, 132-133, 137-138, and 141-142 above, in further view of McCray et al. (Proc AMIA Symp., 2002, pages 504-508; on IDS).

Claims 131 and 140 are further limiting wherein the literature classification system includes MeSH.

Rappaport discloses a method for identifying medical literature as described above.

However, Rappaport does not teach MeSH.

The article of McCray et al. teaches the lexical properties of gene ontology. In particular, McCray et al. studies lexical properties that filter out ill-formed strings in existing biomedical terminology. One of the databases taught in McCray et al. is the MeSH database.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the searching procedures of Rappaport by use of the MeSH database of McCray et al. because it is obvious to try known variants from a finite number of identified, predictable solutions. In this instance, MeSH is one of the databases applicable to the more general databases of Rappaport; one of ordinary skill in the art would have recognized that applying the known technique would have yielded predictable results. There would have been a reasonable expectation of success in that the study of Rappaport is general and applicable to species of databases listed in McCray.

Conclusion

No claim is allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 31 March 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

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Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/

18 June 2008

Russell S. Negin, Ph.D.

/Marjorie Moran/

Supervisory Patent Examiner, Art Unit 1631